

Application Serial No. 09/747,383
Amendment dated April 28, 2005
Response to Office Action of October 29, 2004

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1-15 (canceled)

16. (previously presented): The composition of claim 24, wherein said solution contains at least one million International units of gamma-IFN/ml, as measured by (i) the ability of γ -IFN to stimulate CD64 antigen expression in cultured enriched human monocytes, or (ii) the biological activity of the γ -IFN in solution and droplet form is determined by the ability of γ -IFN to stimulate HLA-DR antigen expression in cultured human monocytes.

17. (previously presented): The composition of claim 24, wherein said solution includes mannitol as a stabilizing agent.

18. (original): The composition of claim 17, wherein said mannitol is present in an amount between 5-15 mM.

19. (previously presented): The composition of claim 24, wherein said solution includes polysorbate as a dispersing agent.

20. (original): The composition of claim 19, wherein the polysorbate is present in an amount between 50-200 mg/liter weight percent.

21. (previously presented): The composition of claim 24, wherein the solution has a viscosity at room temperature of less than 2Cp.

22. (currently amended): A liquid-droplet aerosol composition for delivery to a patient's respiratory tract

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(a) formed from an aqueous γ -IFN solution having a known, selected γ -IFN biological activity, and comprising a dispersing agent and a stabilizing agent in an amount effective to stabilize the γ -IFN upon aerosolization, wherein the stabilizing agent consists consisting of sugar, alcohol, amino acid, or a combination thereof, and wherein the composition does not include serum albumin, and

(b) wherein the aqueous droplets are characterized by

(a)' a narrow particle distribution such that at least 80% of the droplets have a size in a selected size range, wherein the selected size range is selected from the group consisting of (i) less than 1 micron, (ii) 1-3 microns, (iii) 3-5 microns, (iv) 5-10 microns, and (v) greater than 10 microns,

(b)' a γ -IFN biological activity substantially the same as that of the solution; and

(c)' a γ -IFN molecular size distribution substantially the same as that of the solution.

23. (previously presented): The composition of claim 22, wherein at least 95% of the droplets have a size in the selected size range.

24. (currently amended): A liquid-droplet aerosol composition for delivery to a patient's respiratory tract

(a) formed by placing an aqueous γ -IFN solution having a known, selected γ -IFN biological activity, and comprising a stabilizing agent in an amount effective to stabilize the γ -IFN upon aerosolization, and a dispersing agent, wherein the stabilizing agent is a sugar, alcohol, amino acid, or a combination thereof, and wherein the composition does not include serum albumin, against a plate having defined-sized openings, and forcing the solution through said openings, under conditions effective to form aqueous droplets, and wherein the aqueous droplets have ~~having~~

(a)' a narrow distribution of sizes that is less than 2 standard deviations from the volume mean diameter of the droplets, ~~wherein the volume mean diameter is in a selected size range selected from the group consisting of (i) less than 1 micron, (ii) 1-3 microns, (iii) 3-5 microns, (iv) 5-10 microns, and (v) greater than 10 microns~~

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(b)' a γ -IFN biological activity substantially the same as that of the solution, and

(c)' a γ -IFN molecular size distribution substantially the same as that of the solution; and

~~— (b) characterized by an aerosol of aqueous droplets having (a)' a narrow distribution of sizes that is less than 2 standard deviations from the volume mean diameter of the droplets, wherein the volume mean diameter is in a selected size range selected from the group consisting of (i) less than 1 micron, (ii) 1-3 microns, (iii) 3-5 microns, (iv) 5-10 microns, (v) greater than 10 microns, (b)' a γ -IFN biological activity substantially the same as that of the solution, and (c)' a γ -IFN molecular size distribution substantially the same as that of the solution.~~

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